ANGIOLOGICA B.M. Srl	510(K) NOTIFICATION Surgical Mesh	Revision: 1 Date: 02/18/2005

Section 10: 510(K) SUMMARY

510(K) Summary of Safety and effectiveness

Trade names:

REPOL ANGIMESH;
ANGIMESH PRE;
FOLDED MESH;
REPOL PLUG BASIC;
REPOL PLUG CAP;
REPOL PLUG FLOWER;
WINGS MESH;

Common name:

SURGICAL MESH

Classification name:

MESH, SURGICAL, POLYMERIC

Official contact:

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Date:

02/18/2005

Predicate devices:
The SURGICAL MESH - produced by ANGIOLOGICA B.M. S.r.l. - is substantially equivalent to the SURGICAL MESH "BARD MESH", produced by DAVOL INC., Subsidiary of C. R. BARD, INC.

Description:
Monofilament polypropylene mesh, available in various weights, rigidity, shapes and sizes, to allow an easy use in surgical techniques.

Intended use:
REPOL PLUG, ANGIMESH PRE and FOLDED MESH are indicated for the repair of inguinal hernia defects.
REPOL ANGIMESH is indicated to reinforce soft tissue where weakness exists, i.e. repair of hernias.
WINGS MESH is indicated for use in all kind of hernia repair requiring reinforcement with non-absorbable support material.

Comparison to predicate devices:
These devices have the same intended use, the same target population, the same kind of contact (both are implantable devices) and the same technological characteristics (materials, sterility, general shape).

Differences between ANGIOLOGICA B.M. S.r.l. SURGICAL MESH and the predicate device should not affect the safety and effectiveness.
The determination of substantial equivalence is not based on an assessment of performance data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 16 2005

Mr. Roberto Manca
Quality Manager
Angiologica B.M. S.R.L
4, via Giovanni XXIII
San Martino Siccomario, Pavia
Italy 27028

Re: K043191
Trade/Device Name: Repol Angimesh Pre, Folded, Plug Basic, Plug Cap, Plug Flower, Wings Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: April 18, 2005
Received: April 20, 2005

Dear Mr. Manca:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K043191

Indications for Use

510(k) Number (if known): K043191

Device Name: Repol Angimesh Pre, Folded, Plug Basic, Plug Cap, Plug Flower, Wings Mesh

Indications For Use:

Angimesh Pre: "Repair of inguinal hernia defects."

Folded Mesh: "Repair of inguinal hernia defects."

Repol Plug Basic: "Repair of inguinal hernia defects."

Repol Plug Cap: "Repair of inguinal hernia defects."

Repol Plug Flower: "Repair of inguinal hernia defects."

Repol Angimesh: "To reinforce soft tissue where weakness exists, i.e., repair of hernias."

Wings Mesh: "Use in all kind of hernia repair requiring reinforcement with non-absorbable support material."

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

K043191